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SECTION 6 - 510(K) SUMMARY

510(K) Summary
Wisebands™ Skin Closure Device
Wisebands, Ltd.

510(k) Number K.....

Applicant's Name: Wisebands, Ltd.
P.O.B. 978
Ra'anana 43107 ISRAEL
Telephone: +972-9-7747157 Fax: +972-9-7716821

Date Prepared: February, 2000

Trade Name: Wisebands™ Skin Closure Device

Classification Name: System, Skin Closure

Classification: The FDA has classified Skin Closure Device as a class II device (product code MKY) and it is reviewed by the General & Plastic Surgery Panel

Predicate Device: The Wisebands™ Skin Closure device is substantially equivalent to the following devices:
Phoenix ETE Tissue Extension System (Phoenix Biomedical Corp., USA) - K962144, .
STAR Suture Tension Adjustment Reel (Closure Systems LLC) - K904136.
Sure Closure™ Skin Stretching System (Life Medical Sciences, Inc., Israel) - K942526.
Proxiderm Skin Stretching Device (Progressive Surgical Products Inc.) - K982439.
Ethicon Prolene Sutures (Ethicon Inc.) - Preamendment device.
Ethicon Mersilene Polyester 5 mm Tape (Ethicon Inc.) - Preamendment device.
Ethicon Needle (Ethicon Inc.) - Preamendment device.
Deknatel Dacron 3 mm Suture band (Deknatel) - Preamendment device.
Deknatel Dacron vascular tape 6 mm (Deknatel) - K760087.

Performance Standards:

No performance standards have been established for such device under Section 514 of the Federal Food, Drug, and Cosmetic Act.

Indication for Use: The Wisebands™ Skin Closure device is intended for use for closure of surgical skin wounds and prior to a surgical procedure for excision of skin defects.

Device Description: The Wisebands™ Skin Closure Device is designed for gradual closure of skin deficit wounds by exerting controlled tension on a suture band, sewn across the wound/defect and through the skin on the opposite side. Its principle of operation is based on the visco-elastic properties of the skin, which, under mechanical load, can be significantly stretched within a relatively short period of time. The controlled load applied on the suture band causes gradual traction and tension to the skin, so that in a continual process of intermittent tension and relaxation, a complete closure of the wound/defect is achieved. The Wisebands™ Skin Closure device is provided sterile for single use only.

Performance Data: Results from performance testing and biocompatibility testing were provided. The performance testing was conducted to validate that the suture band tensile strength is sufficiently strong for its intended use, that the needle is securely attached to the suture band, and that the tension mechanism on the device releases when tension exceeds 1 kg. Results of this testing confirmed that the device meets its requirements. The biocompatibility testing was performed according to ISO 10993 requirements and included cytotoxicity, acute systemic toxicity, and muscle implantation. Results confirmed that the materials used in the Skin Closure Device are safe for its intended use.

Substantial Equivalence:

Based on the intended use and technological characteristics of the predicate devices, the Wisebands™ Skin Closure device is substantially equivalent to the predicate devices cited above without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 5 2001

Ms. Mary Page
Managing Director
Wisebands Ltd.
P.O.B. 978
Ra'anana 43107 Israel

Re: K002315
Trade Name: Wisebands™ Skin Closure Device
Regulatory Class: I
Product Code: MKY
Dated: December 11, 2000
Received: December 15, 2000

Dear Ms. Page:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K002315

Indications for Use Statement

510(k) Number (if known):_____

Device Name: Wisebands Skin Closure Device

Indications for Use: The Wisebands Skin Closure Device is intended for use for closure of surgical skin wounds and prior to a surgical procedure for excision of skin defects.

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over the Counter Use_____ (Optional Format 1-2-96)

Miriam C Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K002315